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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/595,108

02/17/2006

Murray D. Bailey

13-0128

2759

28519

7590

05/15/2009

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EXAMINER

ROBINSON, BINTA M

ART UNIT

PAPER NUMBER

1625

MAIL DATE

DELIVERY MODE

05/15/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/595,108	Applicant(s) BAILEY ET AL.	
	Examiner BINTA M. ROBINSON	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Applicant's remarks filed 2/13/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20, 23, 25 and 26 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19, 25 and 26 is/are rejected.
- 7) ☒ Claim(s) 27 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

1. Detailed Action

2. The 112, first paragraph rejection, the obvious double patenting rejection over copending application 11766171, and the 102 (e) rejection over Llinas-Brunet et. al. are rendered moot in light of applicant's rejections. Claims 20 and 23 are withdrawn from consideration because they are drawn to non-elected subject matter. The 103(a) rejection over US Patent 7132504 is modified below.

3. (modified)

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-19, 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 7132504 in view of Patani.

'504 teaches the genus of compounds as shown in Formula I, at claim 1, column 78, articles of manufacture containing this compound, and a process of making these compounds. The difference between the prior art compound, articles of manufacture, and a process of making and the instantly claimed compounds, articles of manufacture and a process of making is the teaching of a generic compound, articles of manufacture and a process of making this genus of compounds, is the genus of compounds of formula I, wherein the R5 moiety is B-OC(=O)-and wherein B moiety in the compounds is a fluorinated alkyl in the instant compounds, whereas in the prior art, the preferred embodiments of compounds is where B is -C(=O)-O-unsubstituted alkyl.

Patani et. al. teaches that bioisosterism is one approach used by the medicinal chemist for the rational modification of lead compounds into safer and more clinically effective agents when a lead compound with a desired pharmacological activity may have associated with it undesirable side effects, characteristics that limit its bioavailability, or structural features which adversely influence its metabolism and excretion from the body. See page 3147. The ability of a group of bioisosteres to elicit similar biological activity has been attributed to common physicochemical properties. See page 3148 of Patani et. al. Patani et. al. teaches that the substitution of hydrogen by fluorine is one of the more commonly employed monovalent isosteric replacements. See page 3149 of Patani et. al. It would have been obvious for one of ordinary skill in the art to modify the prior art compounds to synthesize biosiosteres of the prior art compounds to lead to safer, more clinically effective compounds, which are more bioavailable, or better metabolized. Therefore, the compounds, compositions, and process of making them are obvious therefrom in the absence of a showing of unexpected results over the prior art compounds, compositions, and process of making.

Claim 27 is objected to because it is based on a rejected claim.

Response to Applicant's Remarks

Applicant's traverse the 103 (a) rejection over Scola alleging that the preferred embodiments teach away from the prior compounds wherein B is $-\text{C}(=\text{O})-\text{O}$ cycloalkyl. The applicant's make a valid point which has led to a modification of the 103 (a) rejection above. The preferred embodiments in the prior art wherein B is $-\text{C}(=\text{O})-\text{O}$ -unsubstituted alkyl still render obvious the instant compounds where B is a fluorinated

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alkyl in the $\text{BO}(\text{C}=\text{O})$ - moiety because fluorine is a biosisosteric replacement for hydrogen.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Binta M. Robinson whose telephone number is (571) 272-0692. The examiner can normally be reached on M-F (9:30-6:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Janet Andres can be reached on 571-272-0670.

A facsimile center has been established. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier numbers for accessing the facsimile machine are (703)308-4242, (703305-3592, and (703305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571)272-1600.

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/Binta M Robinson/
Examiner, Art Unit 1625

/Janet L. Andres/
Supervisory Patent Examiner, Art Unit 1625